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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,396	01/18/2001	J. Gregor Sutcliffe	22908-0002D1	7291

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/01/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/766,396	Applicant(s) Sutcliffe et al
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 3-19 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 3-19 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

(I. Claims 1-2 & 20, drawn to mammalian cortistatin, and pharmaceutical compositions thereof, classified in class 530, subclass 399) -now cancelled.

II. Claims 3-6, drawn to nucleic acids encoding cortistatin, vectors, and host cells, classified in class 435, subclass 325.

III. Claims 7 & 15-16, drawn to oligonucleotide primers, classified in class 536, subclass 24.33.

IV. Claims 8-9, drawn to antibodies of cortistatin, classified in Class 530, subclass 387.1.

V. Claims 10 & 13, drawn to methods of detecting cortistatin in a sample comprising use of antibodies, and kits thereof, classified in Class 435, subclass 7.1.

VI. Claims 11-12, drawn to methods of detecting cortistatin in a sample comprising detecting nucleic acids, and kits thereof, classified in Class 435, subclass 6.

VII. Claim 14, drawn to a method of detecting mutations in a cortistatin gene that comprises expansion of a CTG domain through nucleotide sequencing, classified in Class 435, subclass 6.

VIII. Claims 17-19, methods of inducing sleep in a mammal comprising administering cortistatin, classified in Class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-IV are directed to products that are physically and functionally distinct; involving proteins, nucleic acids, oligonucleotides and antibodies. All of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Group I and antibodies of Group IV are fundamentally different molecules than the nucleic acid molecules of Groups II or III, For example, the proteins of Group I and antibodies of Group IV are fundamentally different molecules than the nucleic acid molecules of Groups II or III, which in turn can be used to clone the protein, make vaccines, or used as therapeutic agents in gene therapy. Although the antibodies of Group IV can be used in isolating the protein of Group I, the antibodies of Group IV can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The protein of Group I can be utilized in making the antibodies of Group IV, but not vice versa. Although the oligonucleotide primers of Group III and the nucleic acid molecules of Group II are polynucleotides, each of these groups have different structures and functions. Structurally, the

short oligonucleotides of Group II are generally smaller molecules than the nucleic acid molecules of Group I, and do not usually constitute a functional gene. Even though the oligonucleotide primers of Group II can hybridize to the molecules of Group I, these molecules are usually radioactively labeled or biotinylated, or require addition of polymerases to use, which is not required in Group II. In addition, the vectors and host cells of Group II are not required for the products of Groups I, III or IV, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Group I can be used in other materially different methods, such as in affinity chromatography to isolate co-factors or receptor molecules. The method of treating patients with cortistatin of Group VIII requires cells in a patient to treat, as well as administration protocols and assays, which are not required in Group I.

It is noted that the method of Group VIII does not require the products of Groups II-IV, and vice versa.

Groups III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown as stated above (M.P.E.P.

§ 806.05(h)). In the instant case, the oligonucleotides can be used in materially different methods, such as gene therapy, or the prime DNA synthesis. Moreover, the method of Group VII for detecting cortistatin requires either specific tissue or cell preparations, or labeled reagents to detect variations in cortistatin gene expression in a kit, which are not required in Group VI.

It is noted that the method of Groups VII does not require the products of Groups I-II & IV, and vice versa.

Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown as stated above (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of Group IV can be used in other materially different methods, such as in affinity chromatography, or as therapeutic agents. The method of detecting cortistatin in a sample requires specimens and labeled reagents in a kit, which are not required in Group IV.

It is noted that the method of Group V does not require the products of Groups I-III, and vice versa.

Although there are no provisions under the section for "Relation of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different methods; restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups V-VIII are directed to methods of detecting protein or nucleic acid molecules or mutations, or using protein to treat patients. Each of these methods require physically and

functionally distinct elements. For example, the use of antibodies for the method of Group V interact with materially different types of molecules than the nucleic acid molecules used in the methods of Groups VI and VII, or the proteins used in the method of Group VIII, and vice versa. The use of proteins in the method of Group VIII also interact with materially different types of molecules than the nucleic acid molecules used in the methods of Groups VI and VII, and vice versa. The method of Group VIII further requires mammals to treat, unlike the detection methods of Groups V-VII, and vice versa. Lastly, DNA sequencing is required in the method of Group VI, unlike the methods of Groups V, or VII-VIII. These inventions are, therefore, patentably distinct, since one is not required for the other.

3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the materially separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
September 30, 2002

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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